

REMARKS

Claims 1-45 are pending. Claims 4, 5, 11, 14, 18-30, 34, 41 and 44 are withdrawn from consideration. Claims 1-2, 6-10, 13, 15-16, 32, 35-40 and 43 stand rejected under 35 U.S.C. §102(e) as being anticipated by U.S. Patent Publication No. 2003/0104030 to Igaki. Claims 1-2, 6-9, 12-13, 15, 31-32, 35-39 and 42-43 stand rejected under 35 U.S.C. §102(b) as being anticipated by European Patent No. EP 0405284 to Greiner. Claims 3 and 33 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Igaki in view of U.S. Patent No. 6,670,398 to Edwards. Claims 3 and 33 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Greiner in view Edwards. Claims 17 and 45 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Igaki in view of U.S. Patent No. 6,299,604 to Ragheb. Claims 17 and 45 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Greiner in view of Ragheb. Claims 1, 2, 6, 7 and 9 stand rejected on the grounds of nonstatutory obviousness-type double patenting as being unpatentable over claims 40-47, 122-129 and 150-157 of U.S. Patent No. 6,932,930. Claims 31-32, 36-37 and 39 stand rejected on the grounds of nonstatutory obviousness-type double patenting as being unpatentable over claims 40-47, 122-129 and 150-157 of U.S. Patent No. 6,932,930 in view of Greiner.

Applicants have amended independent Claims 1 and 31 to clarify Applicants' invention. New dependent Claim 72 has also been added. Support for the claim amendments can be found on pages 18-19 of Applicants' specification. No new matter has been added. Applicants respectfully traverse the §102 and §103 rejections for the reasons set forth below.

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Double Patenting Rejections Are Overcome

In order to advance the present application to allowance, a Terminal Disclaimer is being filed concurrently, to overcome the non-statutory obviousness-type double patenting rejections. The filing of this Terminal Disclaimer shall not be construed as an admission that the claims are unpatentable under the judicially created doctrine of obviousness-type double patenting or are obvious under 35 USC §103.

§102 Rejections Are Overcome

A claim is anticipated under 35 U.S.C. §102 if each claimed element is found in a single prior art reference. *Scripps Clinic & Research Foundation v. Genentech, Inc.*, 927 F.2d 1565, 1576 (Fed. Cir. 1991); *Carella v. Starlight Archery and Pro Line Co.*, 804 F.2d 135, 138 (Fed. Cir. 1986). There must be no difference between the claimed invention and the reference disclosure, as viewed by an ordinary artisan. *Scripps Clinic & Research Foundation v. Genentech, Inc.*, 927 F.2d at 1576.

Applicants' amended independent Claim 1 recites a method of impregnating an intraluminal prosthesis with a pharmacological agent, comprising:

masking one or more portions of an intraluminal prosthesis with a protective layer of material, wherein the intraluminal prosthesis comprises polymeric material;

immersing the intraluminal prosthesis in a mixture of a carrier fluid and a pharmacological agent;

pressurizing the mixture of carrier fluid and pharmacological agent for a time sufficient to *cause the carrier fluid and pharmacological agent to at least partially penetrate only unmasked portions of the polymeric material*; and

removing the pressure such that the carrier fluid diffuses out of the polymeric material and such that *an amount of the pharmacological agent remains elutably trapped within the unmasked portions of the polymeric material*.

Independent Claim 31 has been similarly amended.

Igaki fails to describe all of the recitations of Claim 1. Igaki describes a stent formed of a biodegradable polymer material that becomes swollen so as to be impregnated with a drug. However, Igaki fails to teach or suggest *masking one or more portions of an intraluminal prosthesis formed of polymeric material with a protective layer of material*, prior to impregnating the polymeric material with a pharmacological agent such that a pharmacological agent at least partially penetrates only *unmasked portions of the polymeric material*, and such that an amount of the pharmacological agent remains elutably trapped within the *unmasked portions of the polymeric material*. Accordingly, Igaki does not anticipate independent Claim 1 or any of the claims depending therefrom. For at least the same reasons, Igaki does not anticipate independent Claim 31 or any of the claims depending therefrom.

Greiner describes a method of impregnating a catheter, made of polymeric material, with a pharmaceutical. The catheter is immersed into a saturated solution of a pharmaceutical in a solvent. The saturated solution serves as a swelling agent and swells the polymeric material of the catheter. The catheter is contacted with the swelling agent at or near supercritical pressure and temperature of the solvent. The pressure is then reduced from supercritical pressure to release the solvent from the catheter, thereby leaving the pharmaceutical impregnated within the catheter. However, Greiner fails to teach or suggest *masking one or more portions of an intraluminal prosthesis formed of polymeric material with a protective layer of material*, prior to impregnating the polymeric material with a pharmacological agent such that a pharmacological agent at least partially penetrates only *unmasked portions of the polymeric material*, and such that an amount of the pharmacological agent remains elutably trapped within the *unmasked portions of the polymeric material*. Accordingly, Greiner does not anticipate independent Claim 1 or any of the claims depending therefrom. For at least the same reasons, Greiner does not anticipate independent Claim 31 or any of the claims depending therefrom.

In view of the above, the rejections under 35 U.S.C. §102 are overcome.

§103 Rejections Are Overcome

Various dependent claims are rejected under §103 based on various combinations of references. For example, Claims 3 and 33 stand rejected as being unpatentable over Igaki in view of Edwards, and over Greiner in view Edwards. Claims 17 and 45 stand rejected as being unpatentable over Igaki in view of Ragheb, and over Greiner in view of Ragheb. The primary references, Igaki and Greiner, have been discussed above and neither teaches nor suggests all of the recitations of independent Claims 1 and 31. The secondary references, Edwards and Ragheb, do not provide rectify the deficiencies of the primary references. Both secondary references fail to teach or suggest ***masking one or more portions of an intraluminal prosthesis formed of polymeric material with a protective layer of material***, prior to impregnating the polymeric material with a pharmacological agent such that a pharmacological agent at least partially penetrates only ***unmasked portions of the polymeric material***, and such that an amount of the pharmacological agent remains elutably trapped within the ***unmasked portions of the polymeric material***. Accordingly, none of the primary and secondary references, alone or in combination, teach or suggest all of the recitations of independent Claims 1 and 31, or any of the claims depending therefrom.

In view of the above, the rejections under 35 U.S.C. §103 are overcome.

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Conclusion

In view of the above, it is respectfully submitted that this application is in condition for allowance, which action is respectfully requested.

Respectfully submitted,

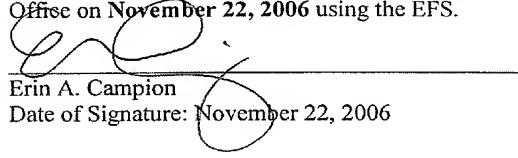


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